Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT A. HOLTON, SEOKCHAN KIM, and YUKIO SUZUKI

Application No. 08/374,520

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, <u>Administrative Patent</u> Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 29-56, all of the claims remaining. Claims 29 and 45 are representative and are reproduced in an appendix to this opinion.

The examiner relies on the following references:

Holton et al. 5,399,726 Mar. 21, 1995 Holton et al. 5,587,489 Dec. 24, 1996

Claims 29-44 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-13 of U.S. Patent 5,399,726.

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Claims 45-56 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-34 of U.S. Patent 5,587,489.

Claims 45-56 stand rejected under 35 U.S.C. § 112, first paragraph, "as being new matter."

We reverse all of the rejections.

<u>Discussion</u>

The claims are directed to derivatives of baccatin III having specified reactive groups at particular positions (claims 45-56), or methods of making such derivatives (claims 29-44). The claimed baccatin III derivatives are useful for making taxol analogs. Specification, pages 2-3.

1. The double patenting rejections

The examiner rejected the process claims under 35 U.S.C. § 101 as claiming the same invention as claimed in U.S. Patent 5,399,726. Similarly, he rejected the product claims as claiming the same invention as claimed in U.S. Patent 5,587,489. He noted that the disclosures of the two patents are identical,¹ and that both are very similar to that of the instant application.² With respect to the process claims, the examiner stated that

[t]he wordings of the patented claims might not be identical to the wordings of the instant claim[s] on the word-by-word basis, but the inventive concept and the contents of the inventions would be deemed identical within the scope of the patent 5,399,726 entitled to for [sic] patent protection against infringement.

Examiner's Answer, page 5. With respect to the product claims, the examiner

¹ The '489 patent is a divisional of the '726 patent.

² The instant application is a continuation-in-part of the '726 patent.

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stated that "the compounds [sic, claims?] of U.S. 5,587,489 would read on the instant claims 45 to 56 which claim the compounds made from the same process on the same ground above regarding to the process rejection." Examiner's Answer, page 6.

We reverse these rejections, because the claims on appeal are not directed to the same invention as the claims of the '726 and '489 patents. The test for "same invention" double patenting is whether the claims of the issued patent could be literally infringed without infringing the application's claims, and vice versa. If one set of claims can be infringed without infringing the other set, the claims are not directed to the same invention and a double patenting rejection under § 101 is improper. See In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 621-22 (CCPA 1970):

The first question in the [double patenting] analysis is: Is the same invention being claimed twice? 35 U.S.C. § 101 prevents two patents from issuing on the same invention. . . . A good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention. . . . If it is determined that the same invention is being claimed twice, 35 U.S.C. § 101 forbids the grant of the second patent.

Here, the application claims define a broader genus of compounds, and methods of making those compounds, than are defined by the claims of the '726 and '489 patents. This is apparent when the structures shown in the instant claims are compared with those of the patent claims. The compound defined in the instant claims includes, inter alia, constituent R₁₄, which can be "hydrogen, alkyl, alkenyl, alkynyl, aryl, or heteroaryl," and constituent R_{14a}, which can be

"hydrogen, alkyl, alkenyl, alkynyl, aryl, or heteroaryl, hydroxy, protected hydroxy, or together with R1 forms a carbonate." In the structures shown in the claims of the '726 and '449 patents, by contrast, the positions corresponding to R_{14} and R_{14a} can only be hydrogens.

Thus, a baccatin III derivative having an alkyl group at positions R_{14} and R_{14a} , or a method of making such a derivative, would infringe the instantly pending claims without infringing the claims of the '726 and '449 patents. This single difference, while not the only difference between the pending and patented claims, is enough in itself to defeat a rejection for "same invention" double patenting. The rejections under 35 U.S.C. § 101 are reversed.

2. The "new matter" rejection

The examiner rejected product claims 45-56 under 35 U.S.C. § 112, first paragraph, as "being new matter." Examiner's Answer, page 4. He explained that "[t]he scope of the claims 45 to 56 is broader than the scope of the original claims which required additional search and/or consideration." Id. Later in the Examiner's Answer, the examiner elaborated on the prosecution history of claims 45-56:

Prior to the first Office action, the compound claims are claims 5 to 8, 25 to 28 with a certain scope. After the first Office action, appellants canceled claims 5 to 8, 25 to 28 and replaced them with the instant claims 45 to 56 (on appeal) with a scope broader than the scope of the original claims 5 to 8 and 25 to 28. The new claims embody various species which are not enabled by the specification such as R_6 and R_{6a} are not hydrogen; R_7 , R_{7a} , R_9 , R_{9a} , R_{10} , R_{10a} are hydrogen; R_{14} and R_{14a} are not hydroxy.

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A rejection of a claim on the basis that it is "new matter" is equivalent to a rejection on the basis that it lacks an adequate written description in the specification. See In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 325 (CCPA 1981) ("Section 132 prohibits the introduction of new matter into the disclosure of an application. Section 112, first paragraph, requires that claim language be supported in the specification. This court, ha[s] said that a rejection of an amended claim under § 132 is equivalent to a rejection under § 112, first paragraph, for lack of support."). See also id. at 1214, 211 USPQ at 326 ("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure . . . is § 112, first paragraph, not § 132.").

The examiner "bears the initial burden . . . of presenting a <u>prima facie</u> case of unpatentability.' <u>In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by 'presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.' . . . If . . . the specification contains a description of the claimed invention, albeit not <u>in ipsis verbis</u> (in the identical words), then the examiner . . ., in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient." <u>In re Alton</u>, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996).

Here, the specification contains a description of baccatin III derivatives that appears to be almost word-for-word the same as the description in, for example, claim 45. See pages 7-9. The examiner nonetheless rejected claim 45, together with claims 46-56, as "being new matter," i.e., lacking an adequate written description. His explanation is that "claims 45 to 56 [are] broader than the scope of the original claims" (Examiner's Answer, page 4) and that "[t]he new claims embody various species which are not enabled by the specification such as R_6 and R_{6a} are not hydrogen; R_7 , R_{7a} , R_9 , R_{9a} , R_{10} , R_{10a} are hydrogen; R_{14} and R_{14a} are not hydroxy." Id., page 6.

This explanation does not meet the examiner's burden of showing that the specification does not adequately disclose the compounds of claims 45-56. The fact that new or amended claims are broader than the original claims is not the test of new matter. The test is whether the new or amended claims are adequately described by the <u>specification</u>. In addition, the examiner has provided no explanation for his conclusory assertion that certain embodiments within the claimed compounds are "not enabled by the specification." To the extent that the assertion is intended to bolster the new matter/written description rejection, we note that all of the species listed in the Examiner's Answer appear to be expressly recited in the specification. See page 7. The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

Other Issues

As discussed above, the instant claims are not identical to those of U.S. Patents 5,399,726 and 5,587,489. The instant claims, however, may be generic

to the claims of the '726 and '489 patents. If so, a rejection for <u>obviousness-type</u> double patenting may be appropriate. See In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015-16 (Fed. Cir. 1993): "If one claimed invention has a broader scope than the other, the [double patenting analysis] must proceed to a second inquiry: whether one claim defines merely an obvious variant of the other patent claim. Without a patentable distinction—because the pending claim defines merely an obvious variation of the patented claim—the patentee may overcome the double patenting rejection by filing a terminal disclaimer." (citation omitted). See also id. at 1052-1053, 29 USPQ2d at 2016: "[The application claims] are generic to the species of invention covered by claim 3 of the patent. Thus, the generic invention is 'anticipated' by the species of the patented invention. This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generic application." (citation and footnote omitted).

See generally In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998) ("Obviousness-type double patenting . . . requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent."); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001) (Obviousness-type double patenting entails a two-step analysis. First, construe the allegedly conflicting claims and, second, determine whether the differences in subject matter between the claims renders the claims patentably distinct. A later patent

claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.).

On return of this case, the examiner should consider whether the instant claims are so closely related to those of the '726 and '489 patents that they are not patentably distinct therefrom. If the pending claims are not patentably distinct from those of the issued patents, a rejection for obviousness-type double patenting should be made.

Summary

We reverse the rejections because the examiner has not shown that the rejected claims are identical to the claims in a previously issued patent or that they lack an adequate written description in the specification.

REVERSED

Sherman D. Winters Administrative Patent Judge))
William F. Smith Administrative Patent Judge)) BOARD OF PATENT
)) APPEALS AND
)) INTERFERENCES
Eric Grimes Administrative Patent Judge)))

Senniger Powers Leavitt and Roedel One Metropolitan Square 16th Floor St Louis MO 63102